



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

Revised Review, May 20, 2011
(Original Review, April 22, 2011)

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 46781-RG, Caviwipes;
DP Barcode: 387061

From: Tajah Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

[Signature]
5/20/11

To: Marshall Swindell PM 33/Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Metrex Research
28210 Wick Road
Romulus, MI 48174

FORMULATION FROM LABEL:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Didecyldimethylammonium chloride.....	0.76%
Ethanol.....	7.50%
Isopropanol.....	15.00%
Inert Ingredients.....	76.74%
Total.....	100.00%

I BACKGROUND

The product, CaviWipes 1 (EPA File Symbol 46781-RG), is a new product. The applicant requested to register the towelette product for use as a disinfectant (bactericide, fungicide, tuberculocide, virucide) and deodorizer on hard, non-porous surfaces in household, institutional, commercial, food preparation, animal care, and hospital or medical environments. The label states that the product is a "one-step" disinfectant. Studies were conducted at MICROBIOTEST, located at 105 Carpenter Drive in Sterling, VA 20164.

This data package contained a letter from the applicant's representative to EPA (dated February 4, 2011), EPA Form 8570-4 (Confidential Statement of Formula), twenty four studies (MRID 483775-10 through 483775-33), Statements of No Data Confidentiality Claims for all twenty four studies, a technical bulletin for the product, and the proposed label.

II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: ambulance equipment, appliance exteriors, barber and salon instruments, basins, bassinets, bathroom fixtures, bathtubs, bed railings, cabinets, cages, carts, chairs, child care equipment, computer keyboards, computers, countertops, cribs, diaper changing stations, diaper pails, diagnostic equipment, doorknobs, examination tables, faucets, filing cabinets, floors, garbage cans, grocery carts, gurneys, hampers, hand rails, handles, headsets, health club equipment, high chairs, infant incubators, infant warmers, kennels, laboratory equipment and surfaces, lamps, light switches, lights, nail care implements, oxygen hoods, patient monitoring equipment, physical therapy equipment, shower stalls, showers, sinks, spine backboards, stethoscopes, stretchers, tables, tanning beds, telephones, toilets, toys, trash cans, trays, ultrasound transducers, urinals, vanity tops, walls, walkers, wheelchairs, and work stations. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: Formica, glass, glazed tile, metal, painted surfaces, plastic (e.g., polycarbonate, polypropylene, polyvinylchloride, polystyrene, vinyl), Plexiglas, and stainless steel. Directions on the proposed label provide the following information regarding use of the product as a disinfectant: Use one towelette to completely pre-clean surface of all gross debris. Use a second towelette to thoroughly wet the surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 1 minute.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes

Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a

simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708; formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using the AOAC Germicidal Spray Products as Disinfectants Method)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Germicidal Spray Products as Disinfectants Method contains procedures for testing fungicidal activity. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Disinfectants for Use as Tuberculocides (Using the AOAC Tuberculocidal Activity of Disinfectants Test Method)

Disinfectants may bear additional label claims of effectiveness as tuberculocides when supported by appropriate tuberculocidal effectiveness data. Certain chemical classes (i.e., glutaraldehyde and quaternary ammonium compounds) are required to undergo validation testing in addition to basic testing. Products that are formulated with other chemical groups do not require validation testing. When using the existing or modified AOAC Tuberculocidal Activity Test Methods, 10 carriers for each of 2 samples, representing 2 different product lots, must be tested against *Mycobacterium bovis* BCG (a member of the *Mycobacterium tuberculosis* species complex). Killing on all carriers/slides as demonstrated in Modified Proskauer-Beck Broth, and no growth in any of the inoculated tubes of 2 additional media (i.e., Middlebrook 7H9 Broth Difco B, Kirchners Medium, and/or TB Broth Base) is required.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides – Novel Virus Protocol Standards

To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory).

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 483775-10 "Testing Pre-Saturated or Impregnated Towelettes for Tuberculocidal Effectiveness – Initial," Test Organism: *Mycobacterium bovis* BCG, for CaviWipes 1, by M. Hamid Bashir. Study conducted at MICROBIOTEST. Study completion date – November 30, 2010. Laboratory Project Identification Number 198-573.

This study was conducted against *Mycobacterium bovis* BCG (obtained from Organon Teknika Corporation). Two lots (Lot Nos. 10-1204 and 10-1208) of the product, CaviWipes 1, were tested using the AOAC Confirmative in vitro Test for Determining Tuberculocidal Activity as described in the AOAC Official Methods of Analysis (edition not specified). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared in accordance with the published AOAC method, with the following exception: (1) the culture suspension was diluted with 9 mL of Modified Proskauer-Beck Medium (which differs from the AOAC method specification of diluting the culture suspension to give 20%T at 650 nm). Heat-inactivated horse serum was added to each culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 21-25 day old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 30 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. Carriers were allowed to remain wet for 1 minute at 21°C. Following exposure, the carriers were transferred to individual tubes of 20 mL of DE Neutralizing Broth. Tubes containing neutralizer were shaken thoroughly after addition of the carrier, as specified in the AOAC method. The carriers were transferred to individual tubes containing 20 mL of Modified Proskauer-Beck Medium. From each tube of neutralizer, 2 mL were cultured to tubes containing 20 mL of Middlebrook 7H9 Broth and 2 mL were cultured to tubes containing 20 mL of Kirchner's Medium. All tubes used for secondary transfers were incubated for 60 days at 37±2°C. The tubes were incubated for an additional 30 days because no growth was observed after 60 days. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness, and confirmation of the challenge microorganism.

Note: Protocol deviations/amendments observed in the current data package.

2. MRID 483775-11 "Testing Pre-Saturated or Impregnated Towelettes for Tuberculocidal Effectiveness – Confirmatory," Test Organism: *Mycobacterium bovis* BCG, for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – November 30, 2010. Laboratory Project Identification Number 198-574.

This confirmatory study was conducted against *Mycobacterium bovis* BCG (obtained from Organon Teknika Corporation). Two lots (Lot Nos. 10-1204 and 10-1208) of the product, CaviWipes 1, were tested using the AOAC Confirmative in vitro Test for Determining Tuberculocidal Activity as described in the AOAC Official Methods of Analysis (edition not specified). The product was received ready-to-use, as a pre-

saturated towelette. A culture of the challenge microorganism was prepared in accordance with the published AOAC method, with the following exception: (1) the culture suspension was diluted with 9 mL of Modified Proskauer-Beck Medium (which differs from the AOAC method specification of diluting the culture suspension to give 20%T at 650 nm). Heat-inactivated horse serum was added to each culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 21-25 day old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 30 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. Carriers were allowed to remain wet for 1 minute at 21°C. Following exposure, the carriers were transferred to individual tubes of 20 mL of DE Neutralizing Broth. Tubes containing neutralizer were shaken thoroughly after addition of the carrier, as specified in the AOAC method. The carriers were transferred to individual tubes containing 20 mL of Modified Proskauer-Beck Medium. From each tube of neutralizer, 2 mL were cultured to tubes containing 20 mL of Middlebrook 7H9 Broth and 2 mL were cultured to tubes containing 20 mL of Kirchner's Medium. All tubes used for secondary transfers were incubated for 60 days at 37±2°C. The tubes were incubated for an additional 30 days because no growth was observed after 60 days. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness, and confirmation of the challenge microorganism.

Note: Protocol deviations/amendments observed in the current data package.

3. MRID 483775-12 "Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Healthcare," Test Organisms: *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442), for CaviWipes 1, by Kathryn D. Dormstetter. Study conducted at MICROBIOTEST. Study completion date – October 25 2010. Amended report date – January 21, 2011. Laboratory Project Identification Number 198-582.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 10-1235, 10-1208, and 10-1204) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995 (modified for towelette products). At least one of the product lots tested (i.e., Lot No. 10-1204) was at least 60 days old at the time of testing. The product was received ready-to-use, as a pre-saturated towelette. Cultures of the challenge microorganisms were prepared. Heat-inactivated horse serum was added to each culture to achieve a 5% organic soil load. Sixty (60) glass microscope slide carriers per product lot per microorganism were inoculated with 0.02 mL of a 47 hour old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 30 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 21°C. Following the exposure period, individual carriers were transferred to 20 mL of DE Neutralizing Broth to

neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48 ± 2 hours at $37 \pm 2^\circ\text{C}$. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness, and confirmation of the challenge microorganisms.

Note: The final report was amended to include information about the organic load in the Test Summary and Conclusions sections of the laboratory report.

Note: Protocol deviations/amendments observed in the current data package.

4. MRID 483775-13 "Pre-Saturated or Impregnated Towelette Initial Virucidal Efficacy Test Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)" for CaviWipes 1, by Helen Christina. Study conducted at MICROBIOTEST. Study completion date – December 30, 2010. Laboratory Project Identification Number 198-586.

This study, under the direction of Study Director Helen Christina, was conducted against Duck hepatitis B virus (Strain LeGarth; obtained from HepadnaVirus Testing, Inc.), using primary duck hepatocytes (ducklings obtained from Metzger Farms) as the host system. Three lots (Lot Nos. 10-1208, 10-1235, and 10-1204) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Initial Virucidal Efficacy Test - Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)," dated November 3, 2010 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 100% duck serum as an organic soil load. Films of virus were prepared by spreading 0.1 mL of virus inoculum over pre-marked bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at room temperature. Five replicates per product lot were tested. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 5 carriers. The carriers were allowed to remain wet for 1 minute at 20°C . Following exposure, each plate was neutralized with 1.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using L-15 Complete. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 20-30 hours at $36 \pm 2^\circ\text{C}$ in $5 \pm 1\%$ CO_2 for viral adsorption. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for 9-13 days at $36 \pm 2^\circ\text{C}$ in $5 \pm 1\%$ CO_2 . The cultures were re-fed, as necessary. Following incubation, the infectious virus was assayed by an immunofluorescence assay. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL ($\text{TCID}_{50}/\text{mL}$) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments observed in the current data package.

5. MRID 483775-14 "Pre-Saturated or Impregnated Towelette Confirmatory Virucidal Efficacy Test Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)" for CaviWipes 1, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – December 21, 2010. Laboratory Project Identification Number 198-587.

This confirmatory study, under the direction of Study Director Salimatu Jibril, was conducted against Duck hepatitis B virus (Strain LeGarth; obtained from HepadnaVirus Testing, Inc.), using primary duck hepatocytes (ducklings obtained from Metzger Farms) as the host system. Three lots (Lot No. 10-1208, 10-1235, and 10-1204) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Confirmatory Virucidal Efficacy Test - Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)," dated November 3, 2010 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 100% duck serum as an organic soil load. Films of virus were prepared by spreading 0.1 mL of virus inoculum over pre-marked bottoms of separate sterile glass Petri dishes. The virus films were dried for 22-30 minutes at room temperature. Five replicates per product lot were tested. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 5 carriers. Carriers were allowed to remain wet for 1 minute at 20-21°C. Following exposure, each plate was neutralized with 1.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. The plates were scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using L-15 Complete. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 20-30 hours at 36±2°C in 5±1% CO₂ for viral adsorption. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for 9-13 days at 36±2°C in 5±1% CO₂. The cultures were re-fed, as necessary. Following incubation, the infectious virus was assayed by an immunofluorescence assay. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL (TCID₅₀/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments observed in the current data package.

6. MRID 483775-15 "Pre-Saturated or Impregnated Towelette Confirmatory Virucidal Efficacy Test Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)" for CaviWipes 1, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – December 21, 2010. Amended report date – January 4, 2011. Laboratory Project Identification Number 198-587.

This confirmatory study, under the direction of Study Director Salimatu Jibril, was conducted against Duck hepatitis B virus (Strain LeGarth; obtained from HepadnaVirus Testing, Inc.), using primary duck hepatocytes (ducklings obtained from Metzger Farms) as the host system. Three lots (Lot No. 10-1208, 10-1235, and 10-1204) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Confirmatory Virucidal Efficacy Test - Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)," dated November 3, 2010 (copy provided). The

product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 100% duck serum as an organic soil load. Films of virus were prepared by spreading 0.1 mL of virus inoculum over pre-marked bottoms of separate sterile glass Petri dishes. The virus films were dried for 22-30 minutes at room temperature. Five replicates per product lot were tested. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 5 carriers. Carriers were allowed to remain wet for 1 minute at 20-21°C. Following exposure, each plate was neutralized with 1.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. The plates were scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using L-15 Complete. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 20-30 hours at 36±2°C in 5±1% CO₂ for viral adsorption. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for 9-13 days at 36±2°C in 5±1% CO₂. The cultures were re-fed, as necessary. Following incubation, the infectious virus was assayed by an immunofluorescence assay. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL (TCID₅₀/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments observed in the current data package.

7. MRID 483775-16 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test Human Immunodeficiency Virus Type 1" for CaviWipes 1, by S. Steve Zhou. Study conducted at MICROBIOTEST. Study completion date – December 21, 2010. Laboratory Project Identification Number 198-588.

This study was conducted against Human immunodeficiency virus type 1 (obtained from ZeptoMetrix), using C8166 cells (obtained from the University of Pennsylvania) as the host system. Three lots (Lot Nos. 10-1208, 10-1235, and 10-1204) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Human Immunodeficiency Virus Type 1," dated November 3, 2010 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.1 mL of virus inoculum uniformly over pre-marked bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at room temperature. Five replicates per product lot were tested. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 5 carriers. The carriers were allowed to remain wet for 1 minute at 20-21°C. Following exposure, each plate was neutralized with 1.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. The plates were scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using RPMI 1640 with 5% fetal bovine serum. C8166 cells in multi-well culture dishes were inoculated eight-fold with selected dilutions. The cultures were incubated for 9-12 days at 36±2°C in 5±1% CO₂. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity,

and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL (TCID₅₀/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments observed in the current data package.

8. MRID 483775-17 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test Herpes Simplex Virus Type 1" for CaviWipes 1, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – December 21, 2010. Laboratory Project Identification Number 198-589.

This study was conducted against Herpes simplex virus type 1 (ATCC VR-260), using Vero cells (ATCC CCL-81) as the host system. Three lots (Lot Nos. 10-1208, 10-1235, and 10-1204) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Herpes Simplex Virus Type 1," dated November 3, 2010 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.1 mL of virus inoculum uniformly over pre-marked bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at room temperature. Five replicates per product lot were tested. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 5 carriers. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of newborn calf serum with 0.87% Polysorbate 80, 0.43% Lecithin, 8.70% HEPES, and 0.0087N HCl. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through Sephadryl columns, and diluted serially in RPMI 1640 with 5% newborn calf serum. Vero cells in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 5-8 days at 36±2°C in 5±1% CO₂. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, column titer, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL (TCID₅₀/mL) was determined using the method of Spearman Karber.

Note: The laboratory reported a failed study set up on November 17, 2010. In the study, a 3-log reduction in titer was not demonstrated due to high levels of cytotoxicity and low virus titers. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. See page 8 of the laboratory report.

Note: Protocol deviations/amendments observed in the current data package.

9. MRID 483775-18 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test Herpes Simplex Virus Type 2" for CaviWipes 1, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – January 4, 2011. Laboratory Project Identification Number 198-590.

This study was conducted against Herpes simplex virus type 2 (ATCC VR-734), using Vero cells (ATCC CCL-81) as the host system. Three lots (Lot Nos. 10-1208, 10-1235, and 10-1204) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Herpes Simplex Virus Type 2," dated November 3, 2010 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.1 mL of virus inoculum uniformly over pre-marked bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at room temperature. Five replicates per product lot were tested. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 5 carriers. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of newborn calf serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through Sephacryl columns, and diluted serially in RPMI 1640 with 5% newborn calf serum. Vero cells in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 5-8 days at 36±2°C in 5±1% CO₂. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, column titer, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL (TCID₅₀/mL) was determined using the method of Spearman Karber.

Note: The laboratory reported a failed study set up on November 17, 2010. In the study, a 3-log reduction in titer was not demonstrated due to high levels of cytotoxicity and low virus titers. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. See page 8 of the laboratory report.

Note: Protocol deviations/amendments observed in the current data package.

10. MRID 483775-19 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test Human Influenza A Virus (H3N2)" for CaviWipes 1, by Helen Christina. Study conducted at MICROBIOTEST. Study completion date – December 6, 2010. Laboratory Project Identification Number 198-591.

This study was conducted against Human influenza A virus (H3N2) (Strain A/Hong Kong/8/68; obtained from Charles River Laboratories), using MDCK cells (ATCC CCL-34) as the host system. Three lots (Lot Nos. 10-1208, 10-1235, and 10-1204) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Human Influenza A Virus (H3N2)," dated November 3, 2010 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.1 mL of virus inoculum uniformly over pre-marked bottoms of separate sterile glass Petri dishes. The

virus films were dried for 20-24 minutes at room temperature. Five replicates per product lot were tested. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 5 carriers. The carriers were allowed to remain wet for 1 minute at 20-21°C. Following exposure, each plate was neutralized with 1.0 mL of Minimal Essential Medium with 5% fetal bovine serum, 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. The plates were scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using Minimal Essential Medium with 1.0 µg/mL trypsin. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 4-6 days at 36±2°C in 5±1% CO₂. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL (TCID₅₀/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments observed in the current data package.

11. MRID 483775-20 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test Adenovirus Type 2" for CaviWipes 1, by Zheng Chen. Study conducted at MICROBIOTEST. Study completion date – January 27, 2011. Laboratory Project Identification Number 198-592.

This study was conducted against Adenovirus type 2 (ATCC VR-846), using A549 cells (ATCC CCL-185) as the host system. Two lots (Lot Nos. 10-1208 and 10-1235) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Adenovirus Type 2," dated October 14, 2010 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.5 mL of virus inoculum over pre-marked bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at room temperature. Each carrier was divided into three sections for treatment: top, middle, and bottom. Each section was wiped with a saturated towelette left to right and back again to the left. A different portion of the towelette was used for each section. The carrier was rotated 90 degrees and the wiping procedure was repeated. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 3 minutes at 20°C. Following exposure, each plate was neutralized with 1.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. The plates were scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using DMEM with 5% fetal bovine serum. A549 cells in multi-well culture dishes were inoculated eight-fold with selected dilutions. The cultures were incubated for 11-14 days at 36±2°C in 5±1% CO₂. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL (TCID₅₀/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments observed in the current data package.

12. MRID 483775-21 "Pre-Saturated or Impregnated Towelette Initial Virucidal Efficacy Test Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C Virus)" for CaviWipes 1, by Zheng Chen. Study conducted at MICROBIOTEST. Study completion date – December 20, 2010. Laboratory Project Identification Number 198-593.

This study, under the direction of Study Director Zheng Chen, was conducted against Bovine viral diarrhea virus (obtained from American BioResearch Laboratories), using MDBK cells (ATCC CCL-22) as the host system. Three lots (Lot Nos. 10-1208, 10-1235, and 10-1204) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Initial Virucidal Efficacy Test - Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C Virus)," dated November 3, 2010 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.1 mL of virus inoculum over pre-marked bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at room temperature. Five replicates per product lot were tested. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 5 carriers. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of horse serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using Minimal Essential Medium with 5% horse serum. MDBK cells in multi-well culture dishes were inoculated eight-fold with selected dilutions. The cultures were incubated for 5-7 days at 36±2°C in 5±1% CO₂. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL (TCID₅₀/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments observed in the current data package.

13. MRID 483775-22 "Pre-Saturated or Impregnated Towelette Confirmatory Virucidal Efficacy Test Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C Virus)" for CaviWipes 1, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – January 4, 2011. Laboratory Project Identification Number 198-594.

This confirmatory study, under the direction of Study Director Salimatu Jibril, was conducted against Bovine viral diarrhea virus (obtained from American BioResearch Laboratories), using MDBK cells (ATCC CCL-22) as the host system. Three lots (Lot No. 10-1208, 10-1235, and 10-1204) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Confirmatory Virucidal Efficacy Test - Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C virus)," dated November 3, 2010 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.1 mL of virus inoculum over pre-marked bottoms of separate sterile glass Petri dishes. The virus films

were dried for 30 minutes at room temperature. Five replicates per product lot were tested. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 5 carriers. Carriers were allowed to remain wet for 1 minute at 20-21°C. Following exposure, each plate was neutralized with 1.0 mL of horse serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. The plates were scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using Minimal Essential Medium with 5% horse serum. MDBK cells in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 5-7 days at 36±2°C in 5±1% CO₂. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL (TCID₅₀/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments observed in the current data package.

14. MRID 483775-23 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test Human Coronavirus (229E strain)" for CaviWipes 1, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – January 4, 2011. Laboratory Project Identification Number 198-597.

This study was conducted against Human coronavirus (Strain 229E; ATCC VR-740), using MRC-5 cells (ATCC CCL-171) as the host system. Three lots (Lot Nos. 10-1208, 10-1235, and 10-1204) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Human Coronavirus (229E strain)," dated November 3, 2010 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.1 mL of virus inoculum over pre-marked bottoms of separate sterile glass Petri dishes. The virus films were dried for 20-25 minutes at room temperature. Five replicates per product lot were tested. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 5 carriers. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.225% Lecithin, 10% HEPES, and 0.01N HCl. The plates were scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using Minimum Essential Medium with 10% fetal bovine serum. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 5-7 days at 33±2°C in 5±1% CO₂. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL (TCID₅₀/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments were observed in the current data package.

15. MRID 483775-24 "Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection – Supplemental – Multi-Drug Resistant *Acinetobacter baumannii*" for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – November 30, 2010. Laboratory Project Identification Number 198-600.

This study was conducted against Multi-Drug Resistant *Acinetobacter baumannii* (ATCC BAA-1605). Two lots (Lot Nos. 10-1208 and 10-1235) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995 (modified for towelette products). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 34 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 21°C. Following the exposure period, individual carriers were transferred to 20 mL of Lethen Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, bacteriostasis, neutralizer effectiveness, antibiotic resistance, and confirmation of the challenge microorganism.

Note: Protocol deviations/amendments were observed in the current data package.

Note: Antibiotic resistance of Multi-Drug Resistant *Acinetobacter baumannii* (ATCC BAA-1605) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, antibiotic disks were placed equidistant from each other on the agar plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibitions (i.e., 0 mm for both disks) confirmed antibiotic resistance of Multi-Drug Resistant *Acinetobacter baumannii* (ATCC BAA-1605) to ceftazidime and gentamicin. See pages 9 and 17 of the laboratory report.

16. MRID 483775-25 "Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection – Supplemental – Methicillin-Resistant *Staphylococcus aureus* (MRSA)" for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – November 29, 2010. Amended report date – January 13, 2011. Laboratory Project Identification Number 198-601.

This study was conducted against Methicillin-Resistant *Staphylococcus aureus* (ATCC 33592). Two lots (Lot Nos. 10-1208 and 10-1235) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995 (modified for towelette products). The product was received ready-to-use, as a pre-saturated

towelette. A culture of the challenge microorganism was prepared. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 40 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 2 t°C. Following the exposure period, individual carriers were transferred to 20 mL of Lethen Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C (which differs from the AOAC method specification of 48 hours at 37°C). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, bacteriostasis, neutralizer effectiveness, antibiotic resistance, and confirmation of the challenge microorganism.

Note: The final report was amended to include information about the organic load in the Conclusions section of the laboratory report.

Note: Antibiotic resistance of Methicillin-Resistant *Staphylococcus aureus* (ATCC 33592) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was placed in the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of Methicillin-Resistant *Staphylococcus aureus* (ATCC 33592) to oxacillin. See pages 9 and t7 of the laboratory report.

Note: Protocol deviations/amendments were observed in the current data package.

17. MRID 483775-26 "Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection – Supplemental – Vancomycin-Resistant *Enterococcus faecalis* (VRE)" for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – November 29, 2010. Amended report date – January 13, 2011. Laboratory Project Identification Number 198-602.

This study was conducted against Vancomycin-Resistant *Enterococcus faecalis* (ATCC 51299). Two lots (Lot Nos. t0-t208 and 10-t235) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, t6th Edition, t995 (modified for towelette products). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 40 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier.

One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 21°C. Following the exposure period, individual carriers were transferred to 20 mL of Lethen Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, bacteriostasis, neutralizer effectiveness, antibiotic resistance, and confirmation of the challenge microorganism.

Note: The final report was amended to include information about the organic load in the Conclusions section of the laboratory report.

Note: Protocol deviations/amendments were observed in the current data package.

Note: Antibiotic resistance of Vancomycin-Resistant *Enterococcus faecalis* (ATCC 51299) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was placed in the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0.45 mm) confirmed antibiotic resistance of Vancomycin-Resistant *Enterococcus faecalis* (ATCC 51299) to vancomycin. See pages 9 and 17 of the laboratory report.

18. MRID 483775-27 "Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection – Supplemental – Vancomycin-Intermediate *Staphylococcus aureus* (VISA)" for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – November 30, 2010. Laboratory Project Identification Number 198-603.

This study was conducted against Vancomycin-Intermediate *Staphylococcus aureus* (ATCC 700699). Two lots (Lot Nos. 10-1208 and 10-1235) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995 (modified for towelette products). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 40 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 21°C. Following the exposure period, individual carriers were transferred to 20 mL of Lethen Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability,

bacteriostasis, neutralizer effectiveness, antibiotic resistance, and confirmation of the challenge microorganism.

Note: Protocol deviations/amendments were observed in the current data package.

Note: Antibiotic resistance of Vancomycin-Intermediate *Staphylococcus aureus* (ATCC 700699) was confirmed by an alternative minimum inhibitory concentration (MIC) broth dilution method. A stock preparation of vancomycin was diluted using Mueller Hinton Broth to yield a series of test concentrations. These were placed into prepared tubes and inoculated with 1 mL of a 1:100 dilution of the bacterial culture. Following incubation, the tubes were observed for growth or no growth. The minimum inhibitory concentration (i.e., 24 µg/mL) confirmed intermediate resistance of Vancomycin-Intermediate *Staphylococcus aureus* (ATCC 700699) to vancomycin. See pages 9, 10, 17, and 22 of the laboratory report.

19. MRID 483775-28 "Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection – Supplemental – Methicillin-Resistant *Staphylococcus epidermidis* (MRSE)" for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – November 29, 2010. Amended report date – January 13, 2011. Laboratory Project Identification Number 198-604.

This study was conducted against Methicillin-Resistant *Staphylococcus epidermidis* (ATCC 51624). Two lots (Lot Nos. 10-1208 and 10-1235) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995 (modified for towelette products). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 40 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 21°C. Following the exposure period, individual carriers were transferred to 20 mL of Letheen Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, bacteriostasis, neutralizer effectiveness, antibiotic resistance, and confirmation of the challenge microorganism.

Note: The final report was amended to include information about the organic load in the Conclusions section of the laboratory report.

Note: Protocol deviations/amendments were observed in the current data package.

Note: Antibiotic resistance of Methicillin-Resistant *Staphylococcus epidermidis* (ATCC 51624) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was placed in the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of Methicillin-Resistant *Staphylococcus epidermidis* (ATCC 51624) to oxacillin. See pages 9 and 17 of the laboratory report.

20. MRID 483775-29 “Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection – Fungicidal – *Trichophyton mentagrophytes*” for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – December 23, 2010. Laboratory Project Identification Number 198-605.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Three lots (Lot Nos. 10-1024, 10-1208, and 10-1235) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995 (modified for towelette products). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 10-15 day old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 40 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 21°C. Following the exposure period, individual carriers were transferred to 20 mL of Neopeptone Glucose Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 10 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness, and confirmation of the challenge microorganism.

21. MRID 483775-30 “Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection – Supplemental – *Klebsiella pneumoniae*” for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – December 14, 2010. Laboratory Project Identification Number 198-606.

This study was conducted against *Klebsiella pneumoniae* (ATCC BAA-1705). Two lots (Lot Nos. 10-1208 and 10-1235) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995 (modified for towelette products). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 48-54 hour old suspension of test

organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 40 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 21°C. Following the exposure period, individual carriers were transferred to 20 mL of Letheen Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, bacteriostasis, neutralizer effectiveness, and confirmation of the challenge microorganism.

22. MRID 483775-31 "Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection – Supplemental – *Bordetella pertussis*" for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – December 30, 2010. Laboratory Project Identification Number 198-607.

This study was conducted against *Bordetella pertussis* (ATCC BAA-589). Two lots (Lot Nos. 10-1208 and 10-1235) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995 (modified for towelette products). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 48-96 hour old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 30 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 21°C. Following the exposure period, individual carriers were transferred to 20 mL of Bordet-Gengou Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. Due to the turbidity of the neutralizer, all subcultures were streaked onto Bordet-Gengou Agar and incubated for 2-5 days at 37±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, bacteriostasis, neutralizer effectiveness, and confirmation of the challenge microorganism.

23. MRID 483775-32 "Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection – Supplemental – *Candida albicans*" for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – November 30, 2010. Laboratory Project Identification Number 198-608.

This study was conducted against *Candida albicans* (ATCC 10231). Two lots (Lot Nos. 10-1208 and 10-1235) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995 (modified for towelette products). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 30 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 21°C. Following the exposure period, individual carriers were transferred to 20 mL of Lethen Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, fungistasis, neutralizer effectiveness, and confirmation of the challenge microorganism.

Note: Protocol deviations/amendments were observed in the current data package.

24. MRID 483775-33 "Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection – Supplemental – Extended Spectrum β -lactamase *Escherichia coli* (ESBL)" for CaviWipes 1, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – November 30, 2010. Laboratory Project Identification Number 198-609.

This study was conducted against Extended Spectrum β -lactamase *Escherichia coli* (ATCC BAA-196). Two lots (Lot Nos. 10-1208 and 10-1235) of the product, CaviWipes 1, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995 (modified for towelette products). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass microscope slide carriers per product lot were inoculated with 0.02 mL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 x 1 inch area of each carrier. The carriers were dried for 34 minutes at 37±2°C. Each carrier was wiped with a saturated towelette with two wipes left to right and two wipes top to bottom for a total of eight passes. A different portion of the towelette was used for each carrier. One towelette was used to treat 10 carriers. The carriers were allowed to remain wet for 1 minute at 21°C. Following the exposure period, individual carriers were transferred to 20 mL of Lethen Broth with 7% Polysorbate 80 and 1% Lecithin to

neutralize. Tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, bacteriostasis, neutralizer effectiveness, antibiotic resistance, and confirmation of the challenge microorganism.

Note: Antibiotic resistance of Extended Spectrum β -lactamase *Escherichia coli* (ATCC BAA-196) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of Extended Spectrum β -lactamase *Escherichia coli* (ATCC BAA-196) to ceftazidime. See pages 9 and 17 of the laboratory report.

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Counts (CFU/ carrier)
		Lot No. 10-1208	Lot No. 10-1235	Lot No. 10-1204	
t-Minute Exposure Time					
483775-12	<i>Staphylococcus aureus</i>	1/60	1/60	0/60	2.6 x 10 ⁵
483775-12	<i>Salmonella enterica</i>	1/60	0/60	0/60	5.4 x 10 ⁵
483775-12	<i>Pseudomonas aeruginosa</i>	1/60	0/60	0/60	1.9 x 10 ⁵
483775-24	Multi-Drug Resistant <i>Acinetobacter baumannii</i>	0/10	0/10	---	2.0 x 10 ⁵
483775-25	Methicillin-Resistant <i>Staphylococcus aureus</i>	0/10	0/10	---	1.8 x 10 ⁵
483775-26	Vancomycin-Resistant <i>Enterococcus faecalis</i>	0/10	0/10	---	3.7 x 10 ⁵
483775-27	Vancomycin-Intermediate <i>Staphylococcus aureus</i>	0/10	0/10	---	4.1 x 10 ⁵
483775-28	Methicillin-Resistant <i>Staphylococcus epidermidis</i>	0/10	0/10	---	3.4 x 10 ⁵
483775-29	<i>Trichophyton mentagrophytes</i>	1/60	0/60	0/60	1.2 x 10 ⁵
483775-30	<i>Klebsiella pneumoniae</i>	0/10	0/10	---	3.4 x 10 ⁵
483775-31	<i>Bordetella pertussis</i>	0/10	0/10	---	1.4 x 10 ⁵
483775-32	<i>Candida albicans</i>	0/10	0/10	---	9.0 x 10 ⁴
483775-33	Extended Spectrum β -lactamase <i>Escherichia coli</i>	0/10	0/10	---	3.0 x 10 ⁵

MRID Number	Organism	Results				Plate Recovery Control
			Lot No. 10-1208	Lot No. 10-1235	Lot No. 10-1204	
1-Minute Exposure Time						
483775-13	Duck hepatitis B virus	10 ⁻² to 10 ⁻³ dilution	Cytotoxicity			10 ^{6.75} TCID ₅₀ /mL
		10 ⁻⁴ to 10 ⁻⁷ dilutions	Complete inactivation			
		TCID ₅₀ /mL	≤10 ^{3.50}	≤10 ^{3.50}	≤10 ^{3.50}	
		Log reduction	≥3.25 log ₁₀	≥3.25 log ₁₀	≥3.25 log ₁₀	
483775-14	Duck hepatitis B virus	10 ⁻² to 10 ⁻³ dilution	Cytotoxicity			10 ^{6.50} TCID ₅₀ /mL
		10 ⁻⁴ to 10 ⁻⁷ dilutions	Complete inactivation			
		TCID ₅₀ /mL	≤10 ^{3.50}	≤10 ^{3.50}	≤10 ^{3.50}	
		Log reduction	≥3.00 log ₁₀	≥3.00 log ₁₀	≥3.00 log ₁₀	
483775-15 Note: Amends 483775-14	Duck hepatitis B virus	10 ⁻² to 10 ⁻³ dilution	Cytotoxicity			10 ^{6.50} TCID ₅₀ /mL
		10 ⁻⁴ to 10 ⁻⁷ dilutions	Complete inactivation			
		TCID ₅₀ /mL	≤10 ^{3.50}	≤10 ^{3.50}	≤10 ^{3.50}	
		Log reduction	≥3.00 log ₁₀	≥3.00 log ₁₀	≥3.00 log ₁₀	
483775-16	Human immuno-deficiency virus	10 ⁻² to 10 ⁻³ dilution	Cytotoxicity			10 ^{7.93} TCID ₅₀ /mL
		10 ⁻⁴ to 10 ⁻⁷ dilutions	Complete inactivation			
		TCID ₅₀ /mL	≤10 ^{4.80}	≤10 ^{4.80}	≤10 ^{4.80}	
		Log reduction	≥3.13 log ₁₀	≥3.13 log ₁₀	≥3.13 log ₁₀	
483775-1	Herpes simplex virus type 1	10 ⁻² dilution	Cytotoxicity			10 ^{8.00} TCID ₅₀ /mL
		10 ⁻³ dilution	Cytotoxicity	Complete inactivation	Cyto-toxicity	
		10 ⁻⁴ to 10 ⁻⁷ dilutions	Complete inactivation			
		TCID ₅₀ /mL	≤10 ^{3.50}	≤10 ^{2.50}	≤10 ^{3.50}	
		Log reduction	≥4.50 log ₁₀	≥5.50 log ₁₀	≥4.50 log ₁₀	
483775-18	Herpes simplex virus type 2	10 ⁻² dilution	Cytotoxicity			10 ^{8.25} TCID ₅₀ /mL
		10 ⁻³ dilution	Cytotoxicity	Complete inactivation	Cytotoxicity	
		10 ⁻⁴ to 10 ⁻⁷ dilutions	Complete inactivation			
		TCID ₅₀ /mL	≤10 ^{3.50}	≤10 ^{2.50}	≤10 ^{3.50}	
		Log reduction	≥4.75 log ₁₀	≥5.75 log ₁₀	≥4.75 log ₁₀	
483775-19	Human influenza A virus (H3N2)	10 ⁻² to 10 ⁻³ dilution	Cytotoxicity			10 ^{6.75} TCID ₅₀ /mL
		10 ⁻⁴ to 10 ⁻⁷ dilutions	Complete inactivation			
		TCID ₅₀ /mL	≤10 ^{3.50}	≤10 ^{3.50}	≤10 ^{3.50}	
		Log reduction	≥3.25 log ₁₀	≥3.25 log ₁₀	≥3.25 log ₁₀	
483775-21	Bovine viral diarrhea virus	10 ⁻² dilution	Cytotoxicity			10 ^{8.93} TCID ₅₀ /mL
		10 ⁻³ to 10 ⁻⁷ dilutions	Complete inactivation			
		TCID ₅₀ /mL	≤10 ^{3.80}	≤10 ^{3.80}	≤10 ^{3.80}	
		Log reduction	≥3.13 log ₁₀	≥3.13 log ₁₀	≥3.13 log ₁₀	

MRID Number	Organism	Results				Plate Recovery Control
			Lot No. 10-1208	Lot No. 10-1235	Lot No. 10-1204	
483775-22	Bovine viral diarrhea virus	10 ⁻² to 10 ⁻³ dilution	Cytotoxicity			10 ^{7.00} TCID ₅₀ /mL
		10 ⁻⁴ to 10 ⁻⁷ dilutions	Complete inactivation			
		TCID ₅₀ /mL	≤10 ^{3.50}	≤10 ^{3.50}	≤10 ^{3.50}	
		Log reduction	≥3.50 log ₁₀	≥3.50 log ₁₀	≥3.50 log ₁₀	
483775-23	Human coronavirus	10 ⁻³ dilution	Cytotoxicity			10 ^{7.00} TCID ₅₀ /mL
		10 ⁻⁴ to 10 ⁻⁷ dilutions	Complete inactivation			
		TCID ₅₀ /mL	≤10 ^{3.50}	≤10 ^{3.50}	≤10 ^{3.50}	
		Log reduction	≥3.50 log ₁₀	≥3.50 log ₁₀	≥3.50 log ₁₀	
3-Minute Exposure Time						
483775-20	Adenovirus type 2	10 ⁻² to 10 ⁻³ dilution	Cytotoxicity	---		10 ^{7.93} TCID ₅₀ /mL
		10 ⁻⁴ to 10 ⁻⁷ dilutions	Complete inactivation	---		
		TCID ₅₀ /mL	≤10 ^{4.80}	≤10 ^{4.80}	---	
		Log reduction	≥3.13 log ₁₀	≥3.13 log ₁₀	---	

MRID Number	Organism	Media	No. Exhibiting Growth/ Total No. Tested	
			Lot No. 10-1204, 90 Days	Lot No. 10-1208, 90 Days
1-Minute Exposure Time				
483775-10	<i>Mycobacterium bovis</i> BCG Carrier Counts: 1.2 x 10 ⁶ CFU/carrier	Modified Proskauer-Beck Medium	0/10	0/10
		Middlebrook 7H9 Broth	0/10	0/10
		Kirchner's Medium	0/10	0/10
483775-11	<i>Mycobacterium bovis</i> BCG Carrier Counts: 1.2 x 10 ⁶ CFU/carrier	Modified Proskauer-Beck Medium	0/10	0/10
		Middlebrook 7H9 Broth	0/10	0/10
		Kirchner's Medium	0/10	0/10

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, CaviWipes 1, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 1-minute contact time:

<i>Staphylococcus aureus</i>	MRID 483775-12
<i>Salmonella enterica</i>	MRID 483775-12
<i>Pseudomonas aeruginosa</i>	MRID 483775-12
Multi-Drug-Resistant <i>Acinetobacter baumannii</i>	MRID 483775-24
Methicillin-Resistant <i>Staphylococcus aureus</i>	MRID 483775-25
Vancomycin-Resistant <i>Enterococcus faecalis</i>	MRID 483775-26
Vancomycin-Intermediate <i>Staphylococcus aureus</i>	MRID 483775-27

Methicillin-Resistant <i>Staphylococcus epidermidis</i>	MRID 483775-28
<i>Klebsiella pneumoniae</i>	MRID 483775-30
<i>Bordetella pertussis</i>	MRID 483775-31
Extended Spectrum β -lactamase <i>Escherichia coli</i>	MRID 483775-33

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. In testing against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*, at least one of the product lots tested was at least 60 days old at the time of testing. Neutralizer effectiveness testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth. When reported, bacteriostasis controls exhibited no growth. The Master label must reflect the antibiotics for which resistance has been demonstrated in order to support a Multi-Drug Resistant claim.

2. The submitted efficacy data support the use of the product, CaviWipes 1, as a disinfectant with fungicidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 1-minute contact time:

<i>Trichophyton mentagrophytes</i>	MRID 483775-29
<i>Candida albicans</i>	MRID 483775-32

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralizer effectiveness testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth. When reported, fungistasis controls exhibited no growth.

3. The submitted efficacy data do not support the use of the product, CaviWipes 1, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of at least a 5% organic soil load for a 1-minute contact time:

Duck hepatitis B virus	MRID 483775-13, -14, and -15
Human immunodeficiency virus type 1	MRID 483775-16
Herpes simplex virus type 1	MRID 483775-17
Herpes simplex virus type 2	MRID 483775-18
Human influenza A virus (H3N2)	MRID 483775-19
Bovine viral diarrhea virus	MRID 483775-21 and -22
Human coronavirus	MRID 483775-23

The towelette guidance requires 1 towelette/10 carriers (1" x 1" size), not 1 towelette/5 carriers or 1 towelette/carrier, with lesser surface areas. The surface area must be equivalent to 10 sq. inches. In the data provided, the surface area represented by the # of tested carriers (5-1" x 1" carriers) does not represent 10 sq. inches (i.e. the result of 10-1" x 1" carriers). Recoverable virus titers of at least 10^4 were achieved. In studies against Duck hepatitis B virus, Human immunodeficiency virus type 1, Herpes simplex virus type 1, Herpes simplex virus type 2, Human influenza A virus (H3N2), Bovine viral diarrhea virus, Human coronavirus, cytotoxicity was observed in the 10^{-2} and/or 10^{-3} dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested.

At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level. In studies against Duck hepatitis B virus and Bovine viral diarrhea virus, the initial and confirmatory studies were performed at the same laboratory but under the direction of different study directors.

4. The submitted efficacy data (MRID No. 483775-20) support the use of the product, CaviWipes t, as a disinfectant with virucidal claims against Adenovirus 2 on hard, non-porous surfaces in the presence of at least a 5% organic soil load for a 3-minute contact time. One carrier represented the required surface area (10 sq. inches) to support the proposed claims. In the future, the dried carrier counts must too reflect the dried carrier amount reflected on t0-t" x t" carriers. Recoverable virus titers of at least 10^4 were achieved. In studies against Adenovirus type 2 cytotoxicity was observed in the 10^{-2} and/or 10^{-3} dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

5. The submitted efficacy data (MRID 483775-10 and -t t) support the use of the product, CaviWipes t, as a disinfectant with tuberculocidal activity against *Mycobacterium bovis* BCG on hard, non-porous surfaces in the presence of a 5% organic soil load for a t-minute contact time. Complete killing was observed in the subcultures of the required number of carriers against the required number of product lots. No growth was observed in the subcultures of the two extra media. Neutralizer effectiveness testing showed positive growth of the microorganism. Viability controls were positive for growth. Sterility controls did not show growth.

VII RECOMMENDATIONS

t. The proposed label claims that the product, CaviWipes t, is an effective "one-step" disinfectant against the following microorganisms on hard, non-porous surfaces for a 1-minute contact time:

Pseudomonas aeruginosa
Staphylococcus aureus
Salmonella enterica

Bordetella pertussis
ESBL *Escherichia coli*
Klebsiella pneumoniae
Methicillin Resistant *Staphylococcus aureus* (MRSA)
Methicillin Resistant *Staphylococcus epidermidis* (MRSE)
~~Multi-drug Resistant~~ *Acinetobacter baumannii*
Vancomycin Resistant *Enterococcus faecalis* (VRE)
Vancomycin Intermediate *Staphylococcus aureus* (VISA)

Candida albicans
Trichophyton mentagrophytes

Mycobacterium bovis BCG

These claims are acceptable as they are supported by the submitted data. The Master label must reflect the antibiotics for which resistance has been demonstrated in order to support a Multi-Drug Resistant claim.

2. The proposed label claims that the product, CaviWipes 1, is an effective "one-step" disinfectant against the following microorganisms on hard, non-porous surfaces for a 1-minute contact time is unacceptable:

- Hepatitis B virus
- Hepatitis C virus
- Herpes simplex virus type 1
- Herpes simplex virus type 2
- Human coronavirus
- Human immunodeficiency virus
- Influenza A H3N2 virus

The surface area tested is not adequate to support towelette claims. These claims are unacceptable and must be removed from the proposed label.

3. The proposed label claims that the product, CaviWipes 1, is an effective "one-step" disinfectant against Adenovirus 2 on hard, non-porous surfaces for a 3-minute contact time. This claim is acceptable, and is consistent with the surface area required to support towelette claims.

4. The use directions for the accepted bactericidal studies differ from the method of application in the test system.

5. The following revisions to the proposed label are recommended:

- On pages 3, 10, and 12 of the proposed label, change "*Klebsiella pneumonia*" to read "*Klebsiella pneumoniae*."
- On page 10 of the proposed label, change "[Kills viruses in 1 minute]" to read "[Kills viruses in 1 minute (Adenovirus 2 in 3 minutes)]."
- On page 12 of the proposed label, change "*Bordatella pertussis*" to read "*Bordetella pertussis*."
- On page 12 of the proposed label, change "Influenza a, H3N2 Virus" to read "Influenza A H3N2 Virus."